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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,368	12/12/2003	Michele Fiscella	PZ045P1D1	2585

22195 7590 12/20/2005

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EXAMINER	
JALLA, SANJOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,368	FISCELLA ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *1-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice to Comply

DETAILED ACTION

1. The examiner of this application in the PTO has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Sanjoo Jalla, Group Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 9/15/05, is acknowledged.
   Claims cancelled: 1-24
   New claims added: 25-48
   Claims 25-48 are under consideration in the instant application.

3. Applicant's election without traverse of group III, claim 13, in the reply filed on 9/15/05 is acknowledged. Furthermore, applicant has elected antibodies that bind the single polypeptide sequence SEQ ID NO: 35.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. However, the use of trademarks has been noted in this application (e.g. ATOVAQUONE™ on page 307). Trademarks should be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any number, which might adversely affect their validity as trademarks.

5. The abstract of the disclosure is objected to as not accurately describing claimed invention. Correction is required. See MPEP § 608.01(b).

6. Applicant's amendment filed 9/15/05 requesting a change of Inventorship is acknowledged. Said request is denied. The agent signing the request does not appear to have power of attorney in this application.

7. This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth herein.

   Upon review of the Sequence Listing, it is noted that the sequence list does not list all inventors or at least 10 inventors.

   Applicants must comply with the requirements of the sequence rules

(37 CFR 1.821-1.825) in response to this Office Action.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The application on page 2 refers to the invention as " relating to polynucleotides and the encoded polypeptides, vectors, host cells, antibodies and recombinant/synthetic methods of producing the polypeptides and polynucleotides. Also diagnostic methods for detecting diseases/disorders related to the polypeptides and therapeutic methods for detecting diseases/disorders related to the polypeptides and therapeutic methods for treating diseases/disorders. Further, the invention relates to screening methods for identifying binding partners of the polypeptides". The claims are directed to an isolated antibody that specifically binds to a protein comprising SEQ ID NO: 35 and fragments of the protein. No activity assays are presented for the protein, nor a specific binding molecule such as a receptor identified. No well-established utility exists for the protein.

The specification on page 11, asserts that polypeptides and antibodies directed to these polypeptides are useful in providing immunological probes for differential identification of the tissue (s)or cell type(s). The specification points to Examples 11, 15 and 18 as exemplification for the use of protein in detection, treatment, and/or prevention of diseases (page 12) ranging from cancer to autism. A review of the examples does not support these assertions. Example 11 discloses the production of secreted proteins for high throughput screening assays, Example 15 discloses a high throughput screening assay for identifying

neuronal activity and Example 18 discloses a high throughput screening assay for identifying changes in small molecule concentration and membrane permeability. It is unclear how any of these examples relate to the intended use of the protein of SEQ ID NO: 35. The specification does not disclose any particular condition wherein there is deficiency, overproduction, or altered form of the protein to which the claimed antibody binds. Clearly, these examples do not provide evidence of a polypeptide that is to be used as described above. Note that no data is provided to support any asserted function. Therefore, the application is devoid of description of utility and working examples of the presently claimed protein function, which is neither clearly defined nor demonstrated.

The specification also asserts that the protein can be used in diagnosing disease for example cancer, this asserted utility is substantial and specific, however, it is not credible. The specification does not disclose any specific diseases associated with altered levels or forms of the protein (SEQ ID NO: 35). Thus, this asserted utility is not credible and there is disclosed insufficient evidence that said utility is substantial, as one of skill in the art would have to engage in further experimentation.

Claims 25-48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-33, 35-44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL accession number AL035289 (Rhodes, Jan- 1999) in view of Campbell (ed.), Monoclonal Antibody

Technology, 1985; 2nd Edition as evidenced by Bost et. al. (Immunological Investigations, 1988; 17: 577-586).

AL035289 teaches a protein that has 72.6% identity with amino acid sequence of SEQ ID NO: 35 of instant application (see a copy of printout of the sequence alignment attached to the office action).

AL035289 does not teach specific antibodies or fragments thereof.

Campbell teaches that it is customary for any group working on protein to make monoclonal antibodies to it (see Chapter 1, page 29, last paragraph). Further, as evidenced by Bost et.al., this antibody would be expected to cross react with other proteins. Bost et. al. teaches an antibody generated against HIV envelope protein that cross reacts with IL-2 even though the sequence homology between the two proteins is of 6 amino acids (see abstract). Further, he teaches that these two peptides might be the cross-reactive epitopes (see page 584, lines 1-2).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to make an antibody as taught by Campbell to the protein as taught by Rhodes that will cross react with protein of SEQ ID NO: 35 that has 72.6% homology with protein of Rhodes.

One of ordinary skill in the art at the time the invention was made would have been motivated to make antibodies (monoclonal, polyclonal or peptide) against the protein of Rhodes (that would also bind the protein of SEQ ID NO: 35) because antibodies are powerful immunochemical tools based on their specificity of binding, their homogeneity and their ability to be produced in large quantities (See Campbell).

From combined teaching of the references, it is apparent that one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

11. Claims 34 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL accession number AL035289 (Rhodes, Jan-1999) in view of Campbell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition, as evidenced by Bost et. al. (Immunological Investigations, 1988; 17: 577-586) as applied to claims 25-33, 35-44 and 46-48 above, and in further view of Gavilondo et. al. (BioTechniques, 2000; 29: 128-145).

AL035289, Campbell and Bost et.al. have been discussed previously.

AL035289 and Campbell do not teach the antibody to be either chimeric or humanized or single chain or a Fab fragment.

Gavilondo et. al. teaches that it was well known in the art at the time the invention was made to prepare antibody fragments, chimeric antibodies, humanized antibodies or single chain antibodies.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Gavilondo et.al. to the antibody of the combined teachings of Rhodes, Bost and Campbell to make a chimeric or humanized or single chain or a Fab fragment antibody.

One of ordinary skill in the art at the time the invention was made would have been motivated to make antibodies (chimeric or humanized or single chain or a Fab fragment antibody) against the protein of Rhodes, because as taught by Gavilaondo et. al. chimeric, humanized and antibody fragments are useful for a number of procedures including purification (e.g. affinity chromatography) and detection assays as well as diagnostic and therapeutic regimens because of their smaller size and potentially better tissue penetration and clearance (see page 132, left column-second paragraph, lines 7-12).

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sanjoo Jalla, Ph.D.
Patent Examiner
Technology Center 1600

11/19/05

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No.	Applicant(s)	
	10/145,012	Nalan Utku et.al.	
	Examiner	Art Unit	
	Sanjoo S. Jalla	1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Corrected Inventorship

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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